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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/526,508

08/09/2005

Hiroyuki Aburatani

392.1001

4237

23280 7590 02/21/2008
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EXAMINER

DAVIS, MINH TAM B

ART UNIT

PAPER NUMBER

1642

MAIL DATE

DELIVERY MODE

02/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/526,508 | Applicant(s) ABURATANI ET AL. | |
| | Examiner MINH-TAM DAVIS | Art Unit 1642 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 15-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 15-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/10/07; 11/13/07; 4/30/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-8, 15-18 are examined in the instant application.

Withdrawn Rejection

The 112, second paragraph, first item has been withdrawn in view of the amendment. The 112, first paragraph, enablement rejection, items # 6 and 9, has been withdrawn in view of the arguments, and amendment, respectively.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons already of record in paper of 05/11/07.

The response asserts that the amendment of claim 3 obviates its rejection.

The response has been considered but is not found to be persuasive for the following reasons:

Rejection remains, because the amended claim 3 now is confusing. Claim 3 is confusing by using the language "having", which is interpreted as having the same meaning as the open language "comprising", and which is, however, followed by a closed language "consisting of".

Claim Rejections - 35 USC § 112, First Paragraph, Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 15-18 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, for reasons already of record in paper of 05/11/07.

1. Claims 1-8, 15-18 are rejected under 112, first paragraph, because the claimed method would not **distinguish** between detection of cancer, including hepatic cancer, and **liver cirrhosis**, and thus one cannot predict that detection of an increase level of soluble GPC3 in serum as compared to normal control indicates the presence of cancer, including hepatic cancer.

The response asserts that amendment of claim 1 to recite basal level of GPC3 obviates the rejection.

The response has been considered but is not found to be persuasive for the following reasons:

It is not clear what constitutes the claimed basal level of GPC3. The specification does not define that basal level of GPC3 includes the level of GPC3 in patients with liver cirrhosis. In view of the teaching of Hippo et al, of record, that the level of soluble GPC3 protein in serum of patient having liver cirrhosis is higher than the corresponding level in healthy controls, the

claimed method would not distinguish between detection of cancer, including hepatic cancer, and liver cirrhosis.

2. Claims 1-8, 15-18 are also rejected under 112, first paragraph, because the claimed method would not **distinguish** between detection of **hepatic** cancer and **melanoma**.

The response asserts that the use of the Nakatsura reference is not appropriate, because it is not a prior art.

The response has been considered but is not found to be persuasive for the following reasons:

It is noted that this is an enablement rejection, and not an art rejection.

NEW REJECTION BASED ON THE AMENDMENT and RECONSIDERATION

Objection

The submitted Appendix A is objected to. Although the response asserts that Appendix A contains experimental data showing overexpression of the soluble protein GPC3 in human patients with hepatic cancer, there is no title or recitation on Appendix A showing that the data is actually GPC3 protein concentration from serum of normal human control and patients with hepatic cancer.

Claim Rejections - 35 USC § 112, Second Paragraph

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is indefinite, because without a sequence identification number for GPC3, there is no reference point for amino acid 1st to amino acid 358th. The N-terminal peptide of GPC3 could be longer than 358 amino acids, and it is not clear whether the 1st amino acid of said N-terminal peptide is the same as the 1st amino acid of the sequence consisting of amino acids 1-358.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LARRY HELMS can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number:
10/526,508
Art Unit: 1643

Page 6

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MINH TAM DAVIS
February 03, 2008

/Larry R. Helms/

Supervisory Patent Examiner, Art Unit 1643